



UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of : **Confirmation No. 9421**
Reynir EYJOLFSSON : Attorney Docket No. 2004_1082A
Serial No. 10/501,454 : Group Art Unit 1616
Filed July 14, 2004 : Examiner Andriae M. Holt
FORMULATIONS OF QUINAPRIL
AND RELATED ACE INHIBITORS : **Mail Stop: RCE**

REPLY SUBMITTED CONCURRENTLY WITH RCE

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

THE COMMISSIONER IS AUTHORIZED
TO CHARGE ANY DEFICIENCY IN THE
FEE FOR THIS PAPER TO DEPOSIT
ACCOUNT NO. 23-0975.

Sir:

In accordance with the RCE submitted herewith, the amendment filed April 25, 2008 will now be entered and considered by the Examiner.

On the Continuation sheet attached to the Advisory Action mailed May 21, 2008, the Examiner states that less than 5wt% of a saccharide compound, in claim 1, continues to read on the rejected claims (the Examiner confirmed during a telephone discussion with Applicants' attorney that she meant to indicate that this reads on the prior art), since less than 5 wt% includes the lower limit of 0 as taught by the prior art.

However, considering the prior art as a whole, Applicants respectfully submit that the presently claimed invention, as set forth in amended claim 1, is not suggested by the prior art. As Applicants have previously noted, the rejections under 35 U.S.C. §103(a) are not based on Harris et al. alone (Example D of this reference discloses a composition with no saccharide), but rather, are based on a combination of Example D of Harris et al. with the Daniel et al. reference. So it is not simply a question of whether or not Harris et al. suggests the presently claimed invention. Rather, the issue is whether or not a combination of Harris et al. with Daniel et al. suggests the invention. In this regard, also as Applicant has previously noted, Example D of

Harris et al. discloses an **inoperative composition** which resulted in an unacceptable amount of hydrolysis product, and in fact illustrates the indispensability of saccharide in the formulations of this reference. On the other hand, in the present invention as set forth in claim 16, the particular combination enables a stabilized formulation which **does not contain saccharide**. Applicants take the position that one of ordinary skill in the art would not have been motivated to add an insoluble alkaline-earth metal salt of hydrogen phosphate (Daniel et al.) to the formulation of Example D of Harris et al., since as indicated above, Example D is an inoperative composition which resulted in an unacceptable amount of hydrolysis product. Under the section of Finding of Obviousness/Rationale and Motivation (MPEP 2142-2143) beginning on page 9 of the Office Action, the Examiner states that it would have been obvious to combine the teachings of the two cited references to produce a stable ACE inhibitor composition because Harris et al. teach it is within the skill of the art to make a stabilized ACE inhibitor composition "comprising an ACE inhibitor, an alkali earth metal carbonate **and a saccharide compound with a weight range between 5% and 90% . . .**" (Emphasis added) However, there is **no motivation** to add the dicalcium phosphate of Daniel et al. to the formulation of Example D of Harris et al. because Example D **does not contain any saccharide compound**. The Examiner has offered no obviousness-rationale or motivation for why one skilled in the art would have added the dicalcium phosphate of Daniel et al. **to the formulation of Example D of Harris et al. which does not contain any saccharide compound**.

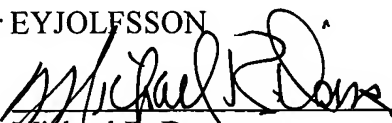
For these reasons, Applicant takes the position that the presently claimed invention is clearly patentable over the applied references.

Therefore, the application is in condition for allowance, and such allowance is solicited.

Respectfully submitted,

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